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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-16-0840]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of

the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Formative Research and Tool Development (OMB Control No. 0920-0840, Expiration 02/29/2016) - Extension - National Center for HIV/AIDS, Viral Hepatitis, STD, TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) requests a three-year approval and extension of the

"Formative Research and Tool Development" generic information collection plan. This information collection request is designed to allow NCHHSTP to conduct formative research information collection activities used to inform many aspects of surveillance, communications, health promotion, and research project development for NCHHSTP's 4 priority diseases (HIV/AIDS, sexually transmitted diseases/infections (STD/STI), viral hepatitis, tuberculosis elimination and the Division of School and Adolescent Health (DASH).

Formative research is the basis for developing effective strategies including communication channels, for influencing behavior change. It helps researchers identify and understand the characteristics—interests, behaviors and needs—of target populations that influence their decisions and actions.

Formative research is integral in developing programs as well as improving existing and ongoing programs. Formative research also looks at the community in which a public health intervention is being or will be implemented and helps the project staff understand the interests, attributes and needs of different populations and persons in that community. Formative research is research that occurs before a program is designed and implemented, or while a program is being conducted.

NCHHSTP formative research is necessary for developing new programs or adapting programs that deal with the complexity of

behaviors, social context, cultural identities, and health care that underlie the epidemiology of HIV/AIDS, viral hepatitis, STDs, and TB in the U.S, as well as for school and adolescent health.

CDC conducts formative research to develop public-sensitive communication messages and user friendly tools prior to developing or recommending interventions, or care. Sometimes these studies are entirely behavioral but most often they are cycles of interviews and focus groups designed to inform the development of a product.

Products from these formative research studies will be used for prevention of HIV/AIDS, Sexually Transmitted Infections (STI), viral Hepatitis, and Tuberculosis. Findings from these studies may also be presented as evidence to disease-specific National Advisory Committees, to support revisions to recommended prevention and intervention methods, as well as new recommendations.

Much of CDC's health communication takes place within campaigns that have fairly lengthy planning periods—timeframes that accommodate the standard Federal process for approving data collections. Short term qualitative interviewing and cognitive research techniques have previously proven invaluable in the development of scientifically valid and population-appropriate methods, interventions, and instruments.

This request includes studies investigating the utility and acceptability of proposed sampling and recruitment methods, intervention contents and delivery, questionnaire domains, individual questions, and interactions with project staff or electronic data collection equipment. These activities will also provide information about how respondents answer questions and ways in which question response bias and error can be reduced.

This request also includes collection of information from public health programs to assess needs related to initiation of a new program activity or expansion or changes in scope or implementation of existing program activities to adapt them to current needs. The information collected will be used to advise programs and provide capacity-building assistance tailored to the identified needs.

Overall, these development activities are intended to provide information that will increase the success of the surveillance or research projects through increasing response rates and decreasing response error, thereby decreasing future data collection burden to the public. The studies that will be covered under this request will include one or more of the following investigational modalities: 1) structured and qualitative interviewing for surveillance, research, interventions and material development, 2) cognitive interviewing for development of specific data collection

instruments, 3) methodological research 4) usability testing of technology-based instruments and materials, 5) field testing of new methodologies and materials, 6) investigation of mental models for health decision-making, to inform health communication messages, and 7) organizational needs assessments to support development of capacity. Respondents who will participate in individual and group interviews (qualitative, cognitive, and computer assisted development activities) are selected purposively from those who respond to recruitment advertisements.

In addition to utilizing advertisements for recruitment, respondents who will participate in research on survey methods may be selected purposively or systematically from within an ongoing surveillance or research project. Participation of respondents is voluntary. The total burden hours are 55,820. There is no cost to participants other than their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Hours Per Response
General public	Screeners Att6	68,208	1	10/60
Healthcare providers	Screeners Att6	29,232	1	10/60

General public	Consent Forms Att9	34,104	1	5/60
Healthcare providers	Consent Forms Att9	14,616	1	5/60
General public	Individual interview Att4	5,544	1	1
Healthcare providers	Individual Interview Att4	2,376	1	1
General Public	Focus Group Interview Att7	3,360	1	2
Healthcare providers	Focus Group Interview Att7	1,440	1	2
General public	Survey of Individual Att5	25,200	1	30/60
Healthcare providers	Survey of Individual Att5	10,800	1	30/60

Leroy A. Richardson,
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